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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,034

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EXAMINER

ZALASKY, KATHERINE M

ART UNIT

PAPER NUMBER

1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,034	Applicant(s) MATTIASSON ET AL.	
	Examiner KATHERINE ZALASKY	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 December 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20051003, 20091207</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Election/Restrictions

1. Applicant's election of group I in the reply filed on 10 August 2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. **Claims 10-18** are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claim Objections

3. **Claims 4 and 5** are objected to because of the following informalities: the claims refer to a polymer and a polysaccharide. **Claim 2**, from which these claims depend, does not include a description of a polysaccharide; therefore, there is a lack of antecedent basis for the polysaccharide recited in **claims 4 and 5**. Appropriate correction is required.

Claim Interpretation

4. It is noted that any limitations which are "optional", "preferable" or conditional, such as the recitation of "when necessary", are not limiting to the claim language.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. **Claims 1-9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bojanic et al. (US 5,417,923) in view of Provonchee et al. (US 5,277,915).

Regarding **claims 1 and 8**, Bojanic et al. discloses a method for the chromatographic separation of substances contained in a liquid sample and a separation device for use in a method for the chromatographic separation of substances contained in a liquid sample (abstract) comprising:

- providing a one piece separation tray having a spaced array of discrete identical upstanding chambers each exhibiting an open upper end and an open lower end and a separation medium placed in at least part of each upstanding chamber (Figure 1, Figure 3, C3/L18-22, C4/L8-23)
- applying a liquid sample to said open upper end of at least one of said upstanding chambers, then applying an eluting liquid to said open upper end of is said at least one of said upstanding chambers; and collecting at least one

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product fraction flowing out from the open lower end of said at least one of said upstanding chambers (C6/L60-68, C7/L43-62)

While the reference does disclose that the separation medium in the chromatography chamber is preferable a monolithic plug which is closely received by the cylindrical bore (C6/L39-46), Bojanic et al. does not disclose that the monolith is a compressible macroporous gel having in its liquid-swollen, non-compressed state a cross-sectional area which is 2-15% larger than the cross-sectional area of the upstanding chamber in which it is placed is used as said separation medium and is in face-to-face contact with the wall of the respective chamber in its liquid-swollen state.

Provonchee et al. discloses a compressible monolithic gel with pores in the range of 0.1 microns to 1000 microns which is suitable for chromatography applications (abstract, C2/L21-26, L32-38). The gel is stronger than conventional gels and is able to be manipulated into various shapes and forms (C2/L52-60). In its compressed/dewatered state, the mass of the gel is 10% to 90% of the mass of the original swollen/watered gel (C2/L32-38). Furthermore, depending on the desired chromatography application, the gel may be derivatized with various functional groups (C5/L45-50).

It would have been obvious to one having ordinary skill in the art at the time of the invention to use the compressible macroporous gel which can be manipulated into various shapes and derivatized with various functional groups for the monolithic stationary phase of Bojanic et al., as taught by Provonchee et al., since doing so provides the separation assay with a mechanically strong and flexible gel which may be modified depending on the desired use. Additionally, it would have been obvious to one having ordinary skill in the art to obtain the details regarding the monolithic stationary phase which are missing from the Bojanic reference

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by performing a literature search, or by reviewing other known documents in the art, such as Provonchee et al.

Regarding **claims 2 and 9**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, Provonchee et al. discloses the method and separation device wherein the monolith of a compressible macroporous gel is a cryogel that has been obtained by polymerizing a solution of one or more monomers selected from the group consisting of: N-substituted and non-substituted (meth)acrylamides, N-alkyl substituted N-vinylamides, hydroxyalkyl (meth)acrylates, vinylacetate, alkylethers of vinyl alcohol, styrene and ring-substituted styrene derivatives, vinyl monomers, (meth)acrylic acid and salts thereof, silicic acid, and monomers capable of forming polymers via polycondensation under freezing at a temperature below the solvent crystallization point, at which solvent in the system is partially frozen with the dissolved substances concentrated in the non-frozen fraction of solvent to the formation of a cryogel (C4/L64-68, polyacrylamides, C4/L47-60).

Regarding **claim 3**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, Provonchee et al. discloses the method wherein the monolith of a compressible macroporous gel is a cryogel that has been obtained by cooling an aqueous solution of polyvinyl alcohol or at least one gel forming polysaccharide selected from the group consisting of agarose, agar, carrageenans, starch and cellulose and their respective derivatives or a mixture of said polysaccharides to a temperature, at which the solvent in the system is partially frozen with the dissolved substances concentrated in the non-frozen fraction of the solvent to the formation of a cryogel, said cooling being carried out, when necessary, in the presence of at least one chaotropic agent in said aqueous solution in order to prevent gel formation before the polymer solution is frozen (C5/L29-35, polysaccharides preferred, C4/L47-60, Example 5, C10/L12-30).

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Regarding **claim 4**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, while Provonchee et al. discloses two separate embodiments, one in which a cross-linked polyacrylamide polymer is used to form the gel and one in which a polysaccharide is used to form the gel, the reference does not disclose that both may be used in the same embodiment and that they become cross-linked. However, it would have been obvious to one having skill in the art to combine the two embodiments such that a combination of cross-linked polymers and polysaccharides are used in the gel formation since doing so amounts to nothing more than the combination of known prior art elements. Additionally, it was known in the art at the time of the invention to form hydrogels from a combination of cross-linked polymers and polysaccharides (as evidenced by Fujii et al., abstract, C7/L11-21).

Regarding **claim 5**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, Provonchee et al. discloses the method wherein the polymer and polysaccharide, respectively, has become modified by introducing a member selected from the group consisting of ligands, charged groups and hydrophobic groups thereinto (C5/L45-50).

Regarding **claim 6**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, while Provonchee et al. discloses that the formed gel may be in the form of a sheet and that because of its strength, it may be easily manipulated into different shapes (C2/L51-60, C6/L45-49), the reference does not disclose that the monolith has been formed by rolling or folding a sheet of a cryogel. However, many methods of placing a monolith into a column are known in the art. For example, Provonchee et al. discloses that a plug of the monolithic material can be inserted into a column (C10/L45-55). Additionally, it is known that monolithic sheets can be rolled into a spiral cylinder or folded into a planar stack for use in a reaction chamber (as evidenced by Bae et al., US 20020169077, abstract). Therefore, it would have been obvious to one having ordinary skill in the art to choose rolling or folding a monolithic

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sheet since doing so amounts to nothing more than a choice from a finite number of identified, predictable solutions for ways to place a monolithic material into a column. Additionally, one would have a reasonable expectation of success since the gel material is disclosed as being strong and easily manipulated into different forms.

Regarding **claim 7**, modified Bojanic discloses all of the claim limitations as set forth above. Additionally, Provonchee et al. discloses the method wherein the monolith of a compressible macroporous gel has been produced by a method selected from the group consisting of: gel formation in double emulsion systems, freeze-drying of a polymer solution, leaching of a particulate material used as a porogen from a preformed polymer monolith, use of gas bubbles as a porogen when gel formation proceeds in foam, and aggregation of polymer particles or fibers (non-woven materials) (C2/L27-41, C4/L47-60).

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE ZALASKY whose telephone number is (571) 270-7064. The examiner can normally be reached on 7:00am - 12:00m Monday and Friday and 7:30am - 6:00pm Tuesday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/
Primary Examiner, Art Unit 1797

/KZ/
16 January 2010